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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,595	01/16/2001	Alan R. Pelton	NDC-15	4295

7590 03/26/2002

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EXAMINER

WILKINS III, HARRY D

ART UNIT	PAPER NUMBER
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1742

DATE MAILED: 03/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

MF-4

Office Action Summary

Application No.

09/760,595

Applicant(s)

PELTON ET AL.

Examiner

Harry D Wilkins, III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☒ Claim(s) 1,2,4,5,7 and 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other:

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "struts 14" are not labeled in the figure. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

2. Claims 1, 2, 4, 5, 7 and 11 are objected to because of the following informalities: in claim 1, line 3, "of" does not fit in grammatically; in claims 2, 4, 5 and 7, line 1, "the said" should be changed to either "the" or "said"; in claim 5, line 2, "at" does not fit in grammatically; and, in claim 11, line 1, the period after "A" should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 12-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The invention is directed to the formation of an oxide surface layer on the surface of a Ni-Ti alloy (see specification page 11, lines 13-17). As

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written, claim 12 is a method whereby the Ni content of the surface is reduced by a surface treatment. The scope of the claims is not fully enabled by the specification in that the inventive method includes reducing the surface Ni content by the preferential formation of a Ti-oxide surface layer and the claimed scope includes reducing the surface Ni content.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakamoto (JP 03-140452) in view of Pelton et al (US 5,843,244).

Sakamoto teaches (see English abstract) that a titanium containing alloy wire is subjected to an oxidizing treatment that selectively oxidizes the titanium, thus forming a surface layer of titanium oxide (TiO₂). Sakamoto teaches (see Figure and definition of "W" on page 2) that the wire is made of a Ni-Ti alloy. Sakamoto teaches (see page 2, upper right) that the alloy has 50-at% Ti (and, thus, 50 at% Ni). This equates to about 55 wt% Ni. Sakamoto teaches that the Ni-Ti alloy is in the form of a wire.

Sakamoto does not expressly teach that the wire is used as a medical device, such as a stent.

Pelton et al teach (see abstract) a method of treating a Ni-Ti shape memory alloy. Pelton et al teach (see paragraph spanning cols 4 and 5) that the inventive method is used to make stents from Ni-Ti shape memory alloys.

Therefore, it would have been obvious to one of ordinary skill in the art to have used the Ni-Ti wire of Sakamoto as a stent because it has shape memory characteristics which allow it to perform the functions of a stent. A stent is a medical device.

Regarding claim 2, Sakamoto teaches that the surface layer oxide is TiO_2 . Thus, the surface contains no Ni.

Regarding claims 3, 4, 5, 7 and 8, each of these claims is a product-by-process claim. Applicant is reminded that for product-by-process claims, the prior art still anticipates the claimed invention, even if made by a materially different method.

Regarding claim 6, Sakamoto teaches (see Figure and definition of "W" on page 2) that the wire is made of a Ni-Ti alloy.

Regarding claims 9 and 10, as stated above, Sakamoto teaches that the alloy contains about 55 wt% Ni.

Regarding claims 11 and 13, Pelton et al teach using a Ni-Ti wire as a stent. Therefore, it would have been obvious to one of ordinary skill in the art to have used the Ni-Ti wire of Sakamoto as a stent because it has shape memory characteristics which allow it to perform the functions of a stent.

Regarding claim 12, Sakamoto teaches a method whereby the surface of a Ni-Ti alloy is exposed to a surface treatment which causes the selective formation of a

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titanium oxide surface layer. This causes the surface to have a "reduced" Ni content with respect to the bulk content of Ni.

7. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakamoto in view of Pelton et al as applied to claims 1-13 above, and further in view of Suzuki et al (US 4,612,061).

As described above, Sakamoto in view of Pelton et al teach the invention substantially as claimed. However, Sakamoto does not teach that the component is exposed to superheated steam.

Suzuki et al teaches (see abstract) a method of forming an oxide surface layer on a metal. The method includes exposing the metal a steam atmosphere.

The oxidation step of Sakamoto and the steam oxidation step of Suzuki et al are considered functional equivalents. The reason that they are considered equivalent is they both perform the same function, i.e.-they both form an oxide surface layer. See MPEP 2144.06.

Therefore, it would have been obvious to one of ordinary skill in the art to have used the steam exposure method of Suzuki et al for the formation of the oxide surface layer in the method of Sakamoto because the two processes are functional equivalents.

Regarding claims 15 and 16, changes in temperature, concentrations, or other process conditions of an old process does not impart patentability unless the recited ranges are critical, i.e., they produce a new and unexpected result. In re Aller et al (CCPA 1955) 220 F2d 454, 105 USPQ 233. Thus, it would have been within the expected skill of a routineer in the art to have optimized the treatment time and

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temperature of the steam exposure in order to create a surface layer that is substantially all TiO₂.

8. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakamoto in view of Pelton et al as applied to claims 1-13 above, and further in view of Mayer et al (US 4,148,699).

As described above, Sakamoto in view of Pelton et al teach the invention substantially as claimed. However, Sakamoto does not teach that the component is immersed in a chemical solution bath for at least about 0.5 hours.

Mayer et al teach (see claim 1) a surface treatment method for stainless steel that includes, as step (3), the formation of an oxide coating by treatment of the workpiece in an aqueous nitric acid bath.

The oxidation step of Sakamoto and the nitric acid bath step of Suzuki et al are considered functional equivalents. The reason that they are considered equivalent is they both perform the same function, i.e.-they both form an oxide surface layer. See MPEP 2144.06.

Therefore, it would have been obvious to one of ordinary skill in the art to have used the nitric acid bath method of Mayer et al for the formation of the oxide surface layer in the method of Sakamoto because the two processes are functional equivalents.

9. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sakamoto in view of Pelton et al as applied to claims 1-13 above, and further in view of Nitowski et al (US 5,277,788).

As described above, Sakamoto in view of Pelton et al teach the invention substantially as claimed. However, Sakamoto does not teach that the component is included as an anode in a solution bath with a current running there through.

Nitowski et al teach (see abstract) that a substrate is anodized (i.e.-used as an anode in a solution bath with current running therethrough) to produce an oxide surface layer.

The oxidation step of Sakamoto and the anodizing step of Nitowski et al are considered functional equivalents. The reason that they are considered equivalent is they both perform the same function, i.e.-they both form an oxide surface layer. See MPEP 2144.06.

Therefore, it would have been obvious to one of ordinary skill in the art to have used the anodizing method of Nitowski et al for the formation of the oxide surface layer in the method of Sakamoto because the two processes are functional equivalents.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- a. Levine (US 3,617,360) teaches a nickel-based alloy article which has an oxide surface coating formed thereon;
- b. Amano et al (US 4,774,150) teaches a thermal barrier coating for a nickel-based superalloy that is made from oxides;
- c. Ono et al (US 4,799,127 and US 4,854,936) teach a nickel-based substrate which has an oxide surface layer formed thereon;

- d. Benum et al (US 5,630,887) describe a method of forming an oxide surface layer where a small amount of steam is added to a reducing gas to preferentially form a Cr oxide surface layer;
- e. Bourdeau (DE 3446180) teaches a Ni-based superalloy that has an Al-oxide surface layer formed thereon;
- f. Watanbe (JP 60-092440) teaches an austenite alloy which forms an Al-oxide surface layer;
- g. Sekine et al (JP 62-174352) teach an alloy that may be mostly Ni which forms an Al₂O₃ film; and,
- h. Sakamoto and Sakamoto et al (JP 03-090555 and JP 03-087349) are related to Sakamoto (JP 03-140452) in that each teaches the formation of a surface oxide layer on a Ni-Ti alloy, though only '452 teaches the selective formation of a titanium surface layer.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Harry D Wilkins, III whose telephone number is 703-305-9927. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy V King can be reached on 703-308-1146. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Harry D Wilkins, III
Examiner
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hdw
March 20, 2002

ROY KING 
SUPERVISORY PATENT EXAMINER
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